

## REMARKS

Claims 1, 3, 4, 6, 7, and 85 are pending in the application.

In the Advisory Action dated July 24, 2003, the Examiner acknowledged that all rejections had been overcome except for obviousness-type double patenting.

### Double Patenting

The only remaining rejection from the December 23, 2002 Office Action is that of obviousness-type double patenting. Claims 1, 3, 4, 6, 7, and 85 remained rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of United States Patent Number 6,268,142. (“‘142”). According to the Examiner, ‘142 claims a method of diagnosing any disease associated with an IL-1 inflammatory haplotype. The Examiner further states that as defined in ‘142 diseases associated with an IL-1 inflammatory haplotype are inclusive of preterm labor and low birth weight. Applicants traverse

Obviousness-type double patenting precludes one person from obtaining more than one valid patent on either (1) the same invention or (2) an obvious modification of the same invention.

The present application does not claim the same invention as the ‘142 patent. The present invention claims a method for determining whether a female subject is predisposed to having a low birth weight baby by detecting an IL-1A (+4845) allele 2 *or* an IL-1B (-511) allele 2. Detection of the allele indicates that the subject is predisposed to having a low birth weight baby. In contrast, the ‘142 patent claims a method of determining a predisposition to a disease associated with an IL-1 inflammatory haplotype by detecting *a pattern of two or more alleles* from a group of alleles of which IL-1A (+4845) allele 2 and an IL-1B (-511) allele 2 are included. Additionally, the ‘142 patent claims that the disease associated with an IL-1 inflammatory haplotype is either an inflammatory disease, a degenerative disease, an immunological disorder, an infectious disease, a trauma induced disease or cancer. The ‘142 patent *does not claim* detecting a predisposition to having a low birth baby by detecting a single allele (i.e., IL-1A (+4845) allele 2 or an IL-1B (-511)) allele 2). Accordingly, Applicants assert that the present invention is not the same invention claimed in the ‘142 patent.

Furthermore, the present application is not an obvious modification of the invention claimed in the '142 patent. The method of the present invention identifies a predisposition to a *specific* disorder --having a low birth baby, by detecting the presence of a *specific* allele--, IL-1A (+4845) allele 2 *or* an IL-1B (-511) allele 2 in a subject. In contrast, the claimed methods of the '142 patent identifies a predisposition to a *large genus* of disorders by detecting a *pattern of two or more alleles*. It would not be obvious to those skilled in the art reading the claims of the '142 patent that a single specific disorder could be identified by a single specific allele as claimed in the present application. Accordingly, Applicants assert that the present invention is not an obvious modification of the invention claimed in the '142 patent. Applicants request that the rejection be withdrawn.

**CONCLUSION**

Applicants respectfully submit that the pending claims are in condition for allowance, and a Notice of Allowance is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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